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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,939	11/07/2001	Harold G. Craighead	1153.009US1	5674
21186	7590	06/25/2004		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/010,939		CRAIGHEAD ET AL.	
	Examiner		Art Unit	
	Brian J. Sines		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 35-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I comprising claims 1 – 25 and 35 – 50 in the reply filed on 4/19/2004 is acknowledged. Claims 26 – 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said binding partner" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 – 11, 13 – 25, 35 – 43 and 45 – 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Lading et al. (U.S. Pat. No. 6,493,090 B1). Regarding claims 1 – 6, Lading

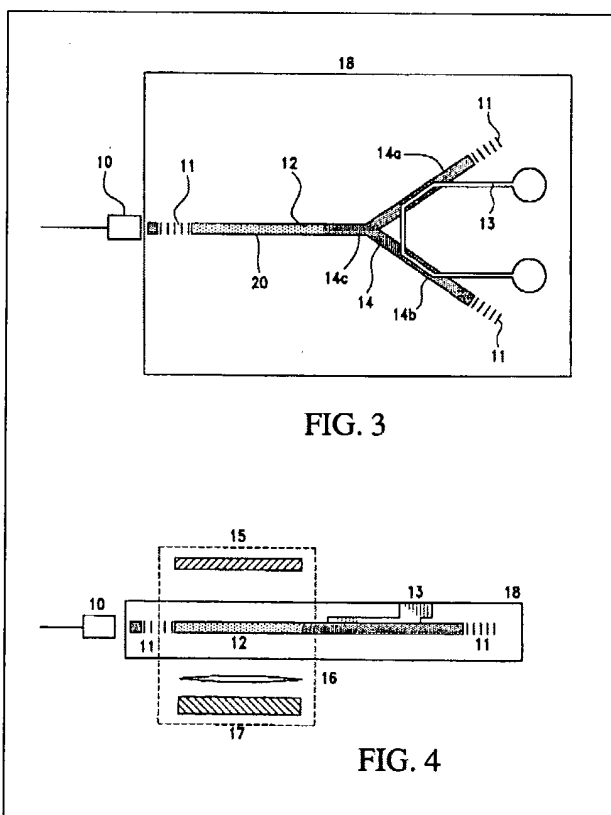
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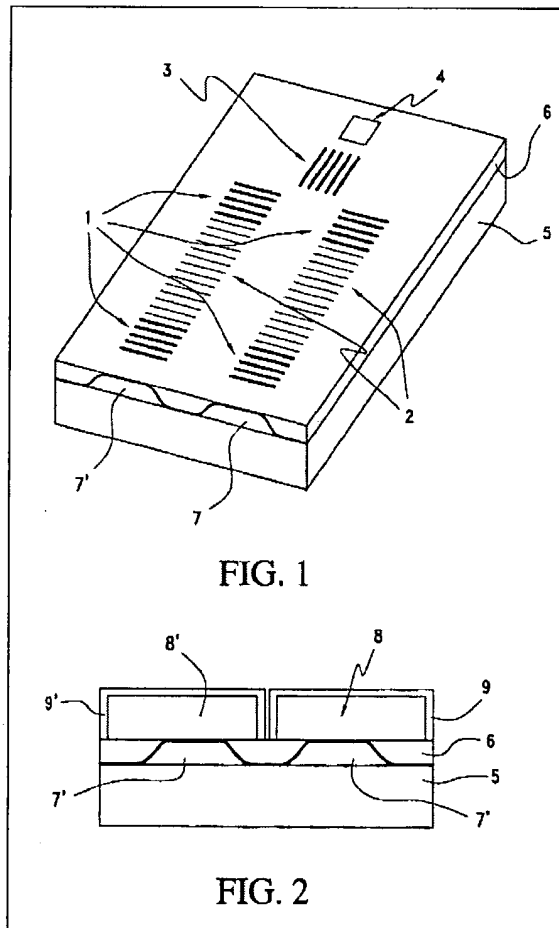
et al. teach an apparatus comprising a duct (e.g., microfluidics handling system 13), wherein the duct has a first wall and a substantially parallel gap formed by a first transparent wall and a second transparent wall (see col. 4, line 15 – col. 14, line 57; figures 1 – 6). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). Regarding claims 7 – 11, Lading et al. anticipate the incorporation of an immobilized binding partner for facilitating analyte detection (see col. 1, lines 1 – 61; col. 4, lines 53 – 59; col. 5, lines 54 – 65; col. 6, lines 41 – 54). Regarding claims 13 – 17 and 20 – 25, 42, 43, and 45 – 50, Lading et al. further anticipate an apparatus comprising: a first translucent plate (e.g., the top of outer walls 9 or 9’); a plurality of sidewalls (e.g., the sidewalls of 9 or 9’); a second translucent plate (substrate 5); a light means or source (e.g., lasers 60 & 62); and a light receiver or sensor means (optical spectrum analyzer 82) (see figures 1, 2, 5 & 6). Lading et al. teach the use of a various types of light detectors, such as photodiodes or photomultiplier tubes for detection (see col. 7, lines 8 – 19). Lading et al. further teach the incorporation of a signal processing means, such as a computer (see col. 8, lines 7 – 10). Lading et al. teach the use of various types of lasers, such as gas lasers, argon lasers, solid state lasers, etc., which are known in the art (see col. 4, lines 60 – 67). Regarding claims 18 and 19, Lading et al. teach the incorporation of prisms as optical elements (see col. 7, lines 26 – 35). Regarding claims 35 – 41, as discussed above, Lading et al. teach all of the structure of the

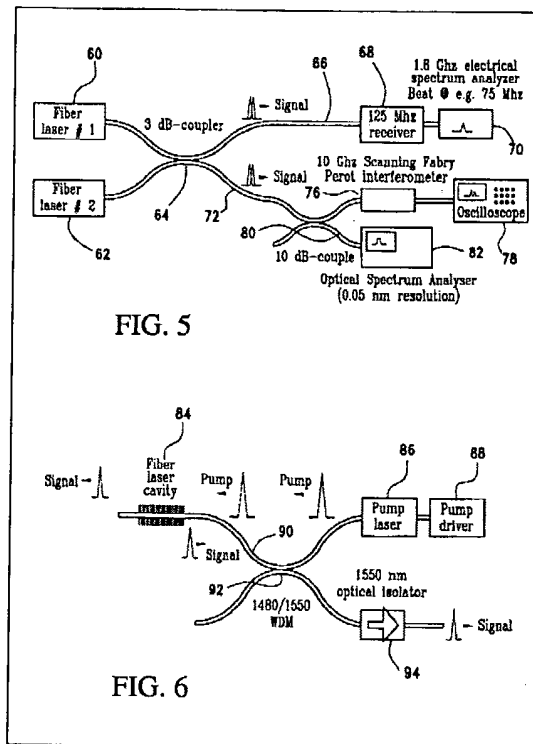
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apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).

The Courts have held that when a prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed that the device will inherently perform the claimed process. See *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). In addition, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01).







Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lading et al. in view of Ebersole et al. (U.S. Pat. No. 5,658,732 A). Lading et al. do not specifically teach the use of an immobilized chelating binding partner. Ebersole et al. do teach the incorporation of a chelating agent with an optical sensor for facilitating optical detection of analytes (see col. 18, lines 40 – 48). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of a chelating agent, as taught by Ebersole et al., with the sensor of Lading et al. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to the use of a chelating agent, as taught by Ebersole et al., with the sensor of Lading et al. in order to facilitate the detection of analytes amenable to binding by chelation.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ridgeway et al. teach an integrated optical refractometer apparatus for performing immunoassays. Wybourne et al. teach optical sensors comprising waveguides incorporating the use of functionalized surfaces for performing biosensing applications. Groger et al. teach a diode laser-based sensor for use in biosensing applications. Gourley teaches an optical detection apparatus for performing cytometry or particle analysis. Craighead et al. teach an optical detection apparatus using an optical waveguide structure. Duveneck et al. teach an optical sensor using a recognition layer. Prass et al. teach an optical sensor which relies upon interference enhanced reflection for detection. Aylott et al. teach an optical sensor incorporating the use of an analyte sensitive layer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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